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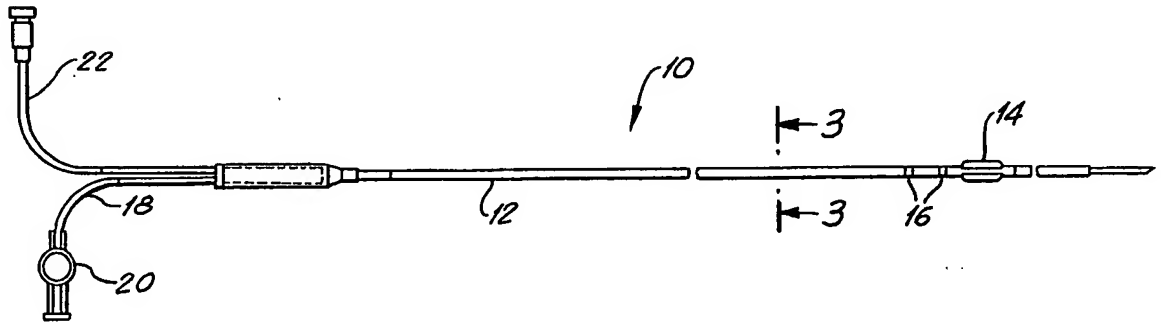
(54) Title: SIZING BALLOON CATHETER



(57) Abstract

Products and methods for sizing openings in body cavities are provided. The products are catheters having compliant balloons attached to their distal ends and reference markers located on the catheter adjacent to the balloons. The preferred device is a cardiovascular sizing balloon for sizing septal defects and includes a latex balloon (14) with a proximal taper (24) and a pair of spaced-apart radiopaque bands (16) located immediately adjacent to the balloon.

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SIZING BALLOON CATHETER

Field of the Invention

This invention relates to a balloon catheter constructed and arranged for sizing openings in body cavities.

Background of the Invention

Balloon catheters are well-known and have been put to various uses in vivo, including occlusion and angioplasty. More recently, balloon catheters constructed for occlusion were used to size cardiovascular openings, in particular septal defects. A septal defect is an abnormal hole in the wall separating the left and right sides of the heart, either between the two atrial or the two ventricle chambers. The defect allows deoxygenated blood in the right side of the heart to mix with oxygenated blood in the left side. The blood pumped from the left side to the body then carries too little oxygen. Such defects may be corrected, for example, by placing an umbrella closure device at the defect. To properly place such a device requires that the defect be accurately sized since the closure device is seated directly on the tissue surrounding the defect. Sizing a septal defect, however, is problematic because septal defects are difficult to visualize using conventional radiography. This problem has been addressed by placing an occlusion balloon across the defect, inflating the balloon with a radiopaque dye, and then estimating the size of the opening by observing the shape of the dye-filled balloon radiographically.

Although the foregoing approach was somewhat successful, it suffered from a variety of drawbacks which could lead to inaccurate measurement of the defect, resulting in failure of the implanted, corrective device.

Summary of the Invention

The invention provides a catheter for sizing an

opening in a body cavity. The catheter includes a compliant balloon attached to the distal end of the catheter and a reference marker located on the catheter adjacent to the balloon. The balloon preferably is constructed and arranged such that it is capable upon inflation of conforming to the opening without substantially distorting the opening. The ability to conform to the opening without distorting it permits an accurate visual image of the opening to be detected (e.g., radiographically). The reference marker provides a scale for determining the error resulting from the detection equipment (e.g., error caused by magnification of a radiographic image). The reference marker preferably is a pair of highly radiopaque bands space at a preselected distance from one another. Methods for sizing an opening in a body cavity also are provided. The balloon catheter of the invention is placed such that the balloon spans an opening, the balloon containing a fluid that permits detection of a represented size of the opening. The represented size of the opening then is compared to the reference markers located on the catheter adjacent to the balloon. In a preferred embodiment, the balloon first is positioned adjacent the opening and is inflated to a diameter larger than the diameter of the opening. The balloon then is moved toward and into the opening until the balloon spans and is centered within the opening. To facilitate this, the balloon is provided with a tapered neck, preferably a tapered proximal neck.

The methods and devices of the invention permit accurate determination of the sizes of body cavity openings, which determinations may be made quickly and easily during in vivo medical procedures.

Brief Description of the Drawings

FIG. 1 depicts a sizing balloon catheter according to the invention.

FIG. 2 is an enlarged, cross-sectional view of the balloon of FIG. 1.

FIG. 3 is an enlarged, cross-sectional view of the catheter of FIG. 1 taken along lines 3-3.

FIG. 4 shows a balloon catheter of the invention with the balloon positioned distally of a defect, but uninflated.

FIG. 5 is the same as FIG. 4, except that the balloon is inflated.

FIG. 6 shows a balloon catheter of the invention with the balloon positioned across a defect and inflated.

Detailed Description of the Preferred Embodiment

The invention relates to methods and devices for determining in vivo the size of a body cavity opening. By body cavity opening, it is meant a narrowed region within a body cavity, such as, a septal defect (e.g., atrial septal defect (ASD) or ventricular septal defect (VSD)). Typically, the balloon catheter of the invention is useful in connection with sizing openings in the vascular system. The balloon catheter may also be useful in connection with sizing openings in other body cavities, such as urological, esophageal or gastroenterological cavities.

A preferred embodiment of a cardiovascular sizing balloon catheter is shown in Fig. 1. This device is particularly useful for sizing ASD, VSD and other congenital defects.

The balloon catheter 10 is a three-lumen polyurethane catheter 12 with a latex balloon 14 attached to its distal end. Just proximal to the latex balloon 14 are a pair of radiopaque reference markers 16. At the proximal end of the device are a balloon leg 18 with a stop cock 20 for receiving a fluid to inflate the balloon and a guide wire leg 22 for receiving a guide wire (not shown) to guide the catheter to the desired location in the body.

The balloon according to the invention is complaint, that is, capable of elastic deformation, preferably at pressures of about 1-2 atmospheres. The balloon is constructed and arranged so that it is capable of conforming upon inflation to a septal defect without substantially distorting the defect. By "substantially distorting", it is meant that only a minimal amount of distortion occurs. Most preferably the balloon is constructed and arranged such that it will conform to that part of the defect which is strong enough to provide a stable platform for an umbrella closure device. In this instance, some slight distortion of the septal defect would occur, and such slight distortion is considered to be embraced within the concept of a balloon that, upon inflation, does not substantially distort the septal defect.

Preferably the balloon when inflated is lemon-shaped; the balloon when inflated has a gradual taper at least at its proximal end, is somewhat rounded through its middle and may be tapered at its distal end as well. By gradual taper it is meant that the balloon has a shape that it is capable of centering of the balloon as it is drawn into the opening, as will be described more fully below in connection with the methods of the invention.

A balloon having the desired shape when inflated may be formed by a coagulant dipping process using a mandrel. The mandrel has the approximate inside shape of the balloon in its uninflated, noncollapsed state (Fig. 2), accounting for shrinkage of the balloon after vulcanization. The preferred balloon forming process involves vertically dipping the mandrel into a salt solution, withdrawing the mandrel from the salt solution, and allowing the solvent to evaporate to produce a semi-dry salt film on the mandrel. The mandrel then is vertically lowered into a latex compound bath, held in the bath and withdrawn. The latex deposit is then vulcanized.

The speed of the dipping and the length of time that the mandrel is held in the baths will depend upon factors well known to those of ordinary skill in the art, such as for example the viscosity of the baths and chemical stability of the latex, keeping in mind the ultimate latex balloon thickness desired. It should be understood that other latex forming methods well known to those of ordinary skill in the art can be employed to produce a latex balloon having the desired shape.

The balloon has a proximal neck 24 of increasing diameter in a distal direction, a mid-portion 26 of uniform diameter, and a distal neck 28 of decreasing diameter in a distal direction. These segments are flanked by a proximal portion 30 and distal portion 32. The distal portion 32 is of uniform diameter and has an I.D. of about 0.074 inches, and an O.D. of about 0.084 inches, defining a wall thickness of about 0.005 inches. The junction 34 of the distal portion 32 and the distal neck 28 has a radius of 0.06 inches. The distal neck 28 extends from the distal portion 32 at an angle of about 30°. The mid portion 26 of the latex balloon 14 has an I.D. of about 0.234 inches and an O.D. of about 0.244 inches, defining a wall thickness of about 0.005 inches. The proximal neck 24 tapers gradually from the mid portion 26 to the proximal portion 30 at a radius of about 0.20 inches. The proximal portion 30 has an I.D. of about 0.085 inches and an O.D. of about 0.093 inches, defining a wall thickness of about 0.004 inches. The proximal neck 24 meets the proximal portion 30 at proximal junction 36. The distance from the distal junction 34 to the proximal junction 36 is about 0.550 inches.

The preferred balloon is made of latex and has a modulus at 500% elongation of about 390 psi, a tensile strength of about 5700 psi and an ultimate elongation at break of about 950%. It is preferred that the minimum modulus at 500% elongation be at least 375 psi, the

minimum tensile strength be at least 4500 psi and the minimum ultimate elongation at break be at least 750%.

The balloon, in its uninflated and collapsed state is capable of being passed through a 10F hole, but is unable to pass through an 8F hole. The balloon preferably is capable of sustaining 20CC inflation of fluid (e.g., water), and the inflated balloon should be free from windows (thin or weak spots) or other visual defects. The openings to be sized by such balloons typically are between 3mm and 30mm. It will be understood, of course, that openings larger and smaller would be sized preferably using balloons having different overall dimensions. The devices according to the invention, however, typically would be used to size openings of between about 1 mm and 25 mm.

The reference marker is a detectable marker of preselected length which may be used as a comparative value for estimating or even measuring the size of an opening. The reference marker should be positioned close enough to the balloon so that the marker may be visualized along with the balloon on the same screen. To permit simultaneous viewing of the balloon and marker on typical radiographic equipment, the markers should be within 5 centimeters of the balloon and preferably within about 2 centimeters of the balloon.

The marker can be highly radiopaque, including those fabricated of gold, platinum, palladium and titanium. The preferred reference marker is a pair of thin, highly radiopaque bands 16, of preselected width and spaced apart from one another at a preselected distance (one cm). Using thin, spaced-apart bands, as opposed to a single, wide band, permits greater catheter flexibility and two points of reference, one being the individual band width and the other being the distance between the leading edges of the bands. Each reference marker 16 is a tantalum band having a width of about 0.040 inches, an

inner diameter of about 0.084 inches and outer diameter of about 0.090 inches, thereby defining a thickness of about 0.003 inches.

The catheter of the preferred embodiment is a three-lumen, polyurethane catheter 12 shown in cross-section in Fig. 3. The catheter 12 has an outer wall 38 that is substantially cylindrical and three web walls 40 that divide the catheter into three lumens. Two smaller lumens 42 are sized such that a circle 44 having a diameter of about 0.021 inches can fit within each of the lumens. These smaller lumens 42 are for inflating and deflating the balloon. A larger lumen 46 is sized such that a circle 48 having a diameter of about 0.041 inches can fit within it. This larger lumen 46 is for receiving a guide-wire. The thickness of the outer wall 38 and web wall 40 is a minimum of about 0.006 inches, and the O.D. of the catheter is about 0.090 inches. The catheter has a roundness of 0.086 inches minimum on any axis and 0.093 inches maximum on any axis. The catheter was fabricated of polyurethane using conventional procedures. The catheter has a tensile strength at break of about 11.3-18.5 lbs, and elongation at break of about 210-380%, and a flexibility at 50° deflection angle of about 0.027 to 0.046 lbs.

Procedures for manufacturing a catheter of the foregoing description are well known to those of ordinary skill in the art. The procedure followed may be summarized briefly as follows. First, the tantalum bands are placed at a desired location on the shaft of the three-lumen polyurethane catheter. This is accomplished by slightly stretching the catheter, not beyond the elastic limit of the material, and sliding the bands into place. Subsequent release of the catheter from the stretching allows the catheter to return to its original shape and dimension, thereby holding the tantalum bands in place. Mandrels are used to maintain lumen patency.

Then, openings or eyes communicating with the smaller lumens 42 are made through the outer wall 38 of the catheter 12 at the distal tip area to permit inflation and deflation of the balloon once the balloon is attached to the catheter. These eyes were separated (as opposed to skiving into both inflation lumens at the same location), so as to decrease the likelihood of the latex balloon occluding the eyes during deflation. In other words, if the balloon were to obstruct the proximal eye during deflation, the distal eye would still be patent and available to complete the deflation process.

The distal tip area of the catheter is shrunk down to provide a lower-profile distal-tip area. This may be accomplished using a silicone tubing sleeve. The silicone tubing first is swelled in freon, and then is allowed to shrink upon the tip of the polyurethane catheter via air drying (freon vaporizes out). The tip area then is heated, and in particular the balloon lumens are heated up to the tip. The silicone tubing next is removed by re-swelling the tubing with freon and sliding it off. An appropriate sized mandrel maintains the larger lumen 46 patency. The tip is trimmed to length and then is rounded off using abrasive stone or paper.

The balloon is attached to the distal end of the catheter by flipping or rolling the ends of the proximal portion 30 and distal portion 34 toward one another to expose their inside surfaces. A bead of adhesive is placed on the shaft at appropriate bond location. The ends are rolled or flipped back such that the inside surfaces of the proximal and distal end portions are in contact with adhesive and are attached to the outside surface of the catheter.

The reference markers are coated with a biocompatible polyurethane composition to provide a smoother transition between the edges of the reference markers and the catheter. The edges of the balloon are

also coated to provide a smoother transition.

The preferred method of using the catheter of the invention may be described with reference to FIGS. 4-6. A guidewire 50 first is positioned across a septal defect 52. The balloon catheter 10 of the invention then is advanced over the guidewire until the latex balloon 14 is positioned distal to the septal defect 52. The balloon is inflated to a volume slightly larger than the defect, preferably using a 4:1 ratio of contrast medium to normal saline. The recommended maximum balloon inflation is about 15cc.

As can be seen, the balloon when inflated has a gradual taper along its proximal neck. This substantially funnel-shaped neck serves dual purposes; it acts to center the catheter (and therefore the balloon) within the opening and to decrease the resistance encountered when drawing the catheter proximally into the opening. Without the taper, centering the balloon both axially and radially is not assured, such centering being important to visualizing the defect.

Using radiographic guidance, the balloon catheter 10 then is slowly withdrawn over the guidewire into the septal defect with the balloon inflated, until the balloon is positioned approximately centrally of the septal defect 52. If resistance is encountered manually or is visualized, the balloon may be partially deflated. The balloon, when positioned across the defect in this manner, will conform to the shape of the septal defect, thereby forming the balloon into the shape of an hourglass. The central portion of the hourglass shape or "waist" of the balloon then represents the size of the opening defined by the septal defect. Using the known 1 cm distance between the marker bands, the size of the opening then may be estimated or even measured directly on the screen of the radiographic equipment.

Those skilled in the art will be able to

ascertain, using no more than routine experimentation, many equivalents of the specific embodiments of the invention described herein. These and all other equivalents are intended to be encompassed by the following claims:

What we claim is:

CLAIMS

1. A balloon catheter for sizing an opening in a body cavity comprising,

a compliant balloon attached to the distal end of the catheter, and

a reference marker located on the catheter adjacent to the balloon.

2. A balloon catheter as claimed in claim 1, wherein the balloon is constructed and arranged such that it is capable upon inflation of conforming to the opening without substantially distorting the opening.

3. A balloon catheter as claimed in claim 2, wherein the balloon is constructed and arranged such that it is capable upon inflation of conforming to the septal defect without substantially distorting the septal defect.

4. A balloon catheter as claimed in claims 1, 2 or 3, wherein the balloon has a proximal end, a distal end, and the balloon is tapered at its proximal end, its distal end or both.

5. A balloon catheter as claimed in claims 1, 2 or 3, wherein the balloon is tapered at its proximal end in its uninflated, noncollapsed state.

6. A balloon catheter as claimed in claims 1, 2 or 3, wherein the balloon is tapered at its proximal end when expanded by inflation.

7. A balloon catheter as claimed in claims 1, 2 or 3, wherein the balloon is made from latex.

8. A balloon catheter as claimed in claims 1,

2 or 3, wherein the balloon has a modulus at 500% elongation of at least 375 psi, a tensile strength of at least 4500 psi and an ultimate elongation at break of at least 750%.

9. A balloon catheter as claimed in claims 1, 2 or 3, wherein the reference marker comprises a pair of spaced-apart radiograph bands.

10. A balloon catheter as claimed in claim 4, wherein the reference marker comprises a pair of spaced-apart radiograph bands.

11. A balloon catheter as claimed in claim 4, wherein the balloon has a modulus at 500% elongation of at least 375 psi, a tensile strength of at least 4500 psi and an ultimate elongation at break of at least 750%.

12. A balloon catheter as claimed in claim 5, wherein the reference marker comprises a pair of spaced-apart radiopaque bands.

13. A balloon catheter for sizing of vascular opening comprising,

a compliant balloon attached to the distal end of a three-lumen catheter, one of the lumens adapted to receive a guide wire, and

a pair of spaced-apart radiopaque bands located adjacent and proximal to the balloon.

14. A balloon catheter as claimed in claim 13 wherein the band closest to the balloon is within two centimeters of the balloon.

15. A balloon catheter as claimed in claim 14 wherein the pair of bands are spaced about 1 centimeter

from one another.

16. A balloon catheter as claimed in claims 13, 14 or 15 wherein the balloon has a tapered proximal neck.

17. A method for sizing an opening in a body cavity in vivo comprising,

placing a balloon of a balloon catheter across the opening, the balloon containing a fluid that permits detection of a represented size of the opening, and

comparing the represented size of the opening to a reference marker located on the catheter adjacent to the balloon.

18. A method as claimed in claim 17 wherein the balloon placed across the opening is constructed and arranged such that it is capable upon inflation of conforming to the opening without substantially distorting the opening.

19. A method as claimed in claim 17 further comprising forming a waist in the balloon at the opening without substantially distorting the size of the opening.

20. A method as claimed in claim 17 wherein a balloon with a tapered proximal neck is placed across the opening.

21. A method as claimed in claims 17, 18 or 20 wherein the balloon is placed across the opening by,

positioning the balloon adjacent to the opening,

inflating the balloon to the diameter larger than the diameter of the opening, and

moving the inflated balloon toward and into

the opening until the balloon spans the opening.

22. A method as claimed in claim 21 wherein the balloon is positioned and is inflated distal to the opening, and then the balloon is withdrawn proximally to place the balloon across the opening.

23. A method for sizing an opening in the vasculature of a patient comprising,

radioscopically detecting both a represented size of the opening, detectable due to the presence of a balloon catheter placed across the opening, and a reference marker of known size located adjacent to the opening, and

comparing the represented size to that of the reference marker.

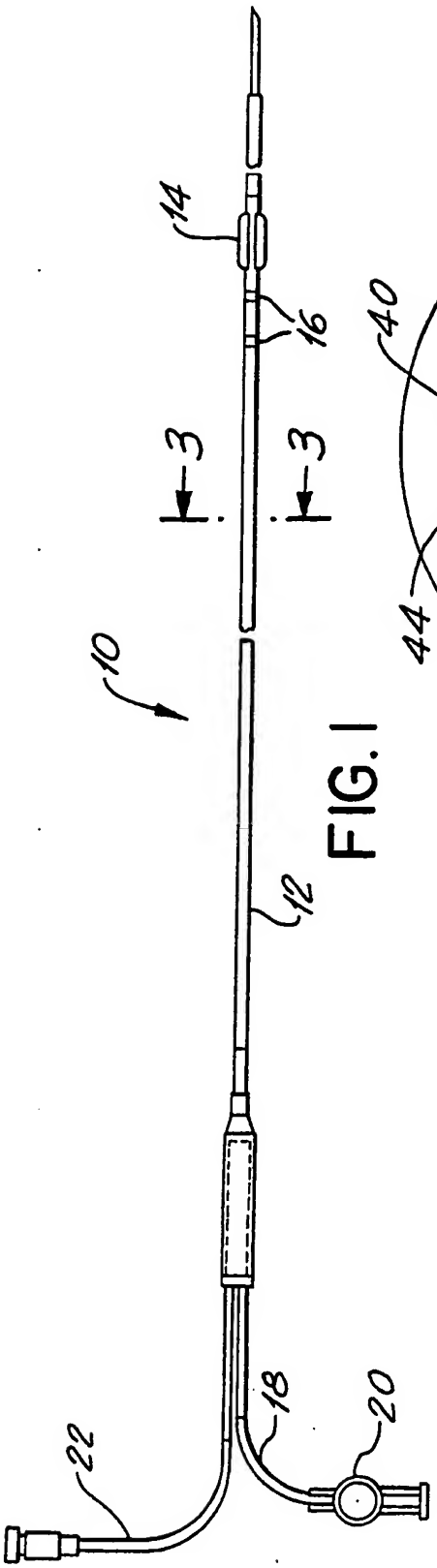

FIG. 1

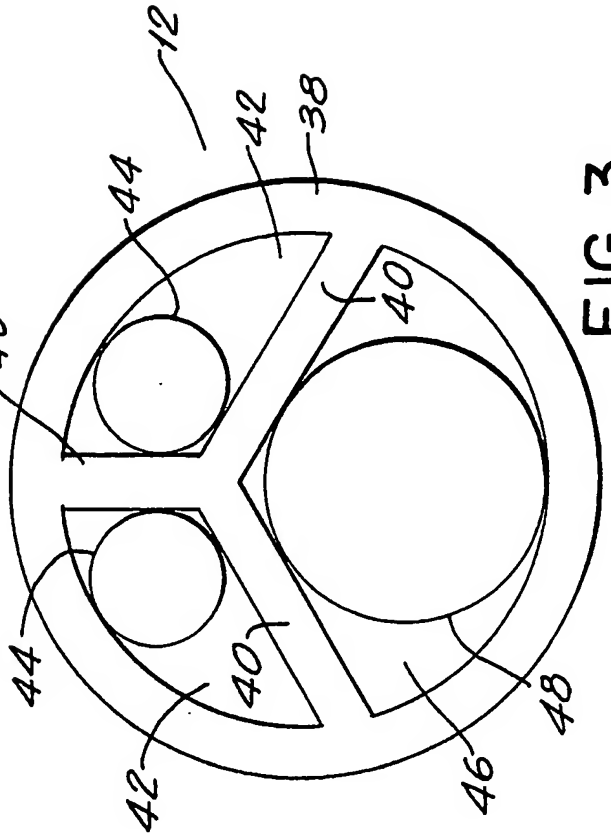

FIG. 3

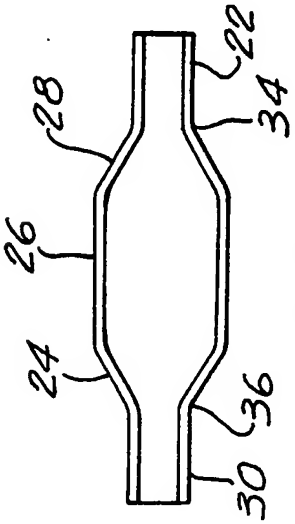

FIG. 2

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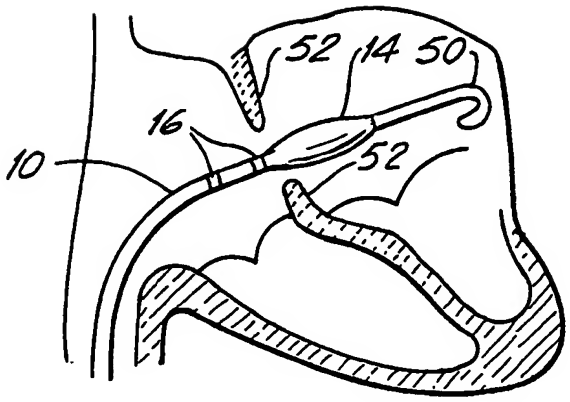

FIG. 4

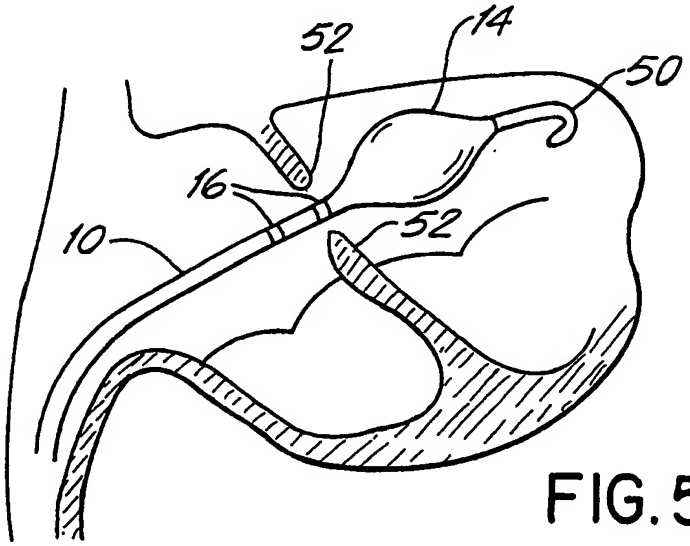

FIG. 5

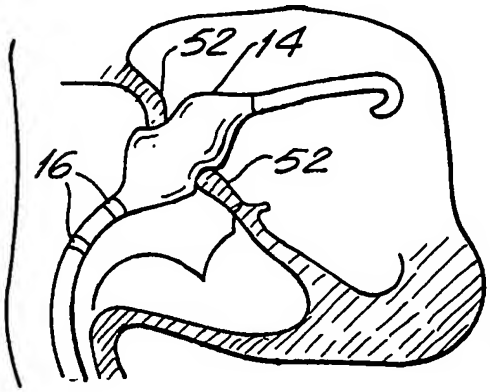

FIG. 6

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/03967

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/107
US CL :606/194; 128/774, 898

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/192, 194, 195; 604/96, 100; 128/774, 898

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 3,978,863 (FETTEL ET AL) 07 September 1976, See entire document.	1-23
Y	US, A, 4,838,879 (TANABE ET AL) 13 June 1989, See entire document.	1-23
Y,E	US, A, 5,108,369 (GANGULY ET AL) 28 June 1992, See entire document.	13-16
Y	US, A, 4,545,390 (LEARY) 08 October 1985, See entire document.	1-12
Y	US, A, 4,630,609 (CHIN) 23 December 1986, See entire document.	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 JUNE 1992	29 JUL 1992
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.	Authorized officer MICHAEL THALER Telephone No. 703-308-0858

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